



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,716	05/28/2008	Suku Thambar	18461-65814	9258

35973 7590 06/24/2010
BINGHAM MCHALE LLP
2700 MARKET TOWER
10 WEST MARKET STREET
INDIANAPOLIS, IN 46204-4900

EXAMINER

MASHACK, MARK F

ART UNIT	PAPER NUMBER
----------	--------------

3773

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

06/24/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

schantz@binghammchale.com
pbailey@binghammchale.com
djones@binghammchale.com

Office Action Summary	Application No. 10/598,716	Applicant(s) THAMBAR ET AL.	
	Examiner MARK MASHACK	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-39,46,47,49 and 50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-39,46,47,49 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/25/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to a communication dated 3/25/2010. Claims 19-39, 46-47, 49-50 are pending.

Response to Arguments

1. Applicant's arguments filed 3/25/2010 have been fully considered but they are not persuasive.
2. Regarding **Claim 19**, Applicant argues "**Bailey** fails to teach or suggest a percutaneous heart valve prosthesis comprising a valve body that tapers linearly from the valve body second end to the valve body first end". Examiner disagrees. Examiner asserts that the valve body first end is considered elements **20, 16** and the valve body second end is considered element **16**. Applicant argues that "**Bailey** fails to teach or suggest sub-fame members of the valve body having the general form of a deltoid with each deltoid having acute-angle vertices at the valve body first and second ends". Examiner disagrees. Examiner asserts that at least the cells which comprise elements **16, 22** are considered the "general form of a deltoid" and have acute angle vertices.
3. Regarding **Claim 19**, Applicant argues "**Seguin** fails to teach or suggest a percutaneous heart valve prosthesis comprising a valve body that tapers linearly from the valve body second end to the valve body first end". Examiner disagrees. Examiner asserts that the "valve second end" can be considered the wider edge of valve segment **10** and the "valve first end" can be considered the combination of valve segments **11, 12**, so that segment **10** comprises the linear taper from the "valve second end" to the

Art Unit: 3773

"valve first end". Examiner asserts that a similar reasonable can be applied, so that segments **12 or 13** can also be considered the linear taper. Regarding **Claim 22**, Applicant argues that **Seguin** "fails to teach or suggest any sub-frame members in the general form of a deltoid having acute-angle vertices at both the valve first and second ends. Examiner disagrees. Examiner asserts that all the cells that comprise the valve body comprise acute-angle vertices (Fig 1) and can be considered at the first end or second end as discussed above. Regarding **Claim 27 and 38**, Applicant argues that **Seguin** "fails to teach or suggest a mitral valve prosthesis". Examiner disagrees. The valve of **Seguin** is capable of serving as a mitral valve prosthesis. Regarding **Claims 28 and 30**, Applicant argues that **Seguin** "fails to teach or suggest locating prongs/barbs spaced about a periphery of the valve second end". Examiner disagrees. Examiner asserts that according the interpretation that either segments **12 or 13** can be considered the linear taper as stated about the valve second end can be considered the combination of segments **10, 11 or 10, 11, 12**. Applicant argues that **Seguin** "fails to teach or suggest blocking of blood flow in a direction through the passage of the valve body from the valve body second end to the valve body first end. Examiner disagrees. According to the interpretation that segment **13** comprises the linear taper, the prior art still reads on the claim limitations.

4. Regarding **Claim 19**, Applicant argues "the **Cribier** prosthesis does not taper from one end to the second end". "A concave shape clearly suggests a double tapered or hourglass type of configuration , which is consistent with the arrangement". Examiner disagrees. Examiner asserts that the valve second end can be considered the wider

Art Unit: 3773

side of either of the tapers and the valve first end can be considered the other side of the taper. Regarding **Claim 22**, Applicant argues that **Cribier** "fails to teach or suggest sub-frame members of the valve body having the general form of a deltoid having acute-angle vertices at the valve body first and second ends". Examiner disagrees.

Examiner asserts that **Cribier** clearly discloses of the stent cells being of the general form of a deltoid and having acute-angle vertices. Applicant argues that **Cribier** "fails to teach or suggest a collapsible diagonal element extending between oblique angle vertices...

the recitilinear struts (17) extend longitudinally between the first and second ends of the valve body, a distance away from the oblique-angle vertices of the individual sub-frame elements". Examiner disagrees. Examiner asserts that "extending between" does not require contact between the two elements. Examiner asserts that the diagonal elements **17** extend between apices since they are diagonally inclined to block the blood flow (Fig 4b).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 19-24, 27, 29, 49** are rejected under 35 U.S.C. 102(b) as being anticipated by **Bailey et al. ("Bailey" US 6,458,153)**.

Art Unit: 3773

Bailey discloses a percutaneous heart valve comprising: a valve body **12** ; one or more flexible valve elements **26**; said valve body tapers from one end to a second end such that one end is sized to pass through a valve orifice and a second end being sized not to pass through the valve orifice (FIG 1-5, 6, 12, 13-17). The valve body comprises a superelastic memory material (Column 5, Lines 33-40). Sub-frame members with general deltoids/rhombus shapes with acute angle vertices at said first and second ends and obtuse angle vertices between can be appreciated (e.g. members of element **16** and **22**). The sub-frame members are joined at the vertices by diagonal elements (e.g. members of element **20**) which secures the valve elements **26** (FIG 2). The prosthesis is a mitral valve prosthesis (Column 9, Line 61, - Column 10, Line 14). The sub-frame members are joined at respective oblique-angled vertices (FIG 1). The flange elements **22** comprise prongs. An elongate guide element **222** is detachable attached to the valve and is capable of extending beyond catheter **210** (Column 13, Lines 15-21).

Examiner asserts that the valve body first end is considered elements **20**, **16** and the valve body second end is considered element **16**. Examiner asserts that at least the cells which comprise elements **16**, **22** are considered the “general form of a deltoid” and have acute angle vertices.

7. **Claims 19-24, 27-28, 30-35, 38, 49-50** are rejected under 35 U.S.C. 102(b) as being anticipated by **Seguin (WO 03/003949 translated into US 2005/0043790)**.

Art Unit: 3773

Sequin discloses a valve body having a valve body first end, a valve body second end, a passage; one or more flexible valve elements **4**; a plurality of prongs **15**; wherein said valve body tapers such that one end is sized to pass through an orifice and one end sized not to pass. The valve is intended to be delivered via a collapsed configuration by a catheter (Paragraph 50) and is intended to be made a superelastic material (Paragraph 48). The valve body comprises at least three rhombus-shaped sub-frame members (cells comprising elements **10** and **12**) and prongs **15**.

. Examiner asserts that the “valve second end” can be considered the wider edge of valve segment **10** and the “valve first end” can be considered the combination of valve segments **11**, **12**, so that segment **10** comprises the linear taper from the “valve second end” to the “valve first end”. Examiner asserts that a similar reasonable can be applied, so that segments **12 or 13** can also be considered the linear taper. The valve of **Sequin** is capable of serving as a mitral valve prosthesis. Examiner asserts that according the interpretation that either segments **12 or 13** can be considered the linear taper as stated about the valve second end can be considered the combination of segments **10, 11** or **10, 11, 12**. Regarding Claims 49-50, according to the interpretation that segment **13** comprises the linear taper, the prior art still reads on the claim limitations.

8. **Claims 19-20, 22-26** are rejected under 35 U.S.C. 102(b) as being anticipated by **Cribier et al. (“Cribier” US 2003/0014104)**.

Cribier discloses a percutaneous heart valve prosthesis comprising: a valve body **10** which tapers from one end to the second end to maintain the valve in position (Paragraph 41); one or more flexible valve elements **14**; the valve body comprises at least three valve body sub-frame members having the shape of a deltoid or rhombus and joined at the oblique vertices (FIG 3b). The subframe member further comprise collapsible diagonal member **17** extending between said oblique-angled vertices secured to said valve elements (Paragraph 93).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. **Claims 30-38** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Cribier** in view of **Seguin et al.** ("**Seguin**" US 2004/0093060).

Cribier discloses all of the claimed limitations except for a plurality of prongs spaced. However, **Seguin** teaches of a similar valve prosthesis comprising a plurality of prongs (Paragraph 10). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of **Cribier** with prongs in order to ensure proper positioning (Paragraph 7).

11. **Claims 39** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Seguin** in view of **Bailey**.

Seguin discloses all of the claimed limitations except for the means of delivering the valve. However, **Bailey** teaches of a similar valve and a delivery catheter comprising an elongate guide element **222** is detachable attached to the valve and is capable of extending beyond catheter **210** (Column 13, Lines 15-21). It would have been obvious to modify the device of **Seguin** with the delivery catheter of **Bailey** in order to facilitate navigating the vasculature.

12. **Claims 46** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bailey** in view of **Goar et al.** ("**Goar**" **US 2004/0039442**).

Bailey discloses of the device of Claims 19 and a method of treating a failed or failing mitral valve (FIG 12A-B and Column 11, Lines 13-27). In another embodiment, **Bailey** explicitly discloses advancing the catheter **503** past the valve being treated and wedging the valve body into the orifice in order to dilate the valve orifice (FIG 20 and Column 14, Lines 6-55). The valve body is partially advanced through the catheter for deployment prior to the wedging (Column 14, Lines 19-28); however, the claim language, as written, does not require that chronological aspect of the sequence. It would have been obvious or inherent to advance the catheter into the left atrium while treating the mitral valve in order to perform the valvuplasty step. **Bailey** does not explicitly disclose of how the catheter would be positioned in the left atrium. However, **Goar** teaches of a method of accessing the mitral valve through the right and left atrium

Art Unit: 3773

via a trans-septal puncture (FIG 8). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of **Bailey** with the trans-septal puncture to facilitate the positioning of the catheter in the left atrium.

13. **Claims 47** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Cribier** in view of **Seguin** as in Claim 30 and further in view of **Bailey** and **Goar et al.** ("**Goar**" US 2004/0039442).

Cribier in view of **Seguin** disclose of the device of Claims 30 and a method of treating a failed or failing mitral valve (**Cribier** Paragraph 75). **Bailey** explicitly teaches of advancing the catheter **503** past the valve being treated and wedging the valve body into the orifice in order to dilate the valve orifice (FIG 20 and Column 14, Lines 6-55). The valve body is partially advanced through the catheter for deployment prior to the wedging (Column 14, Lines 19-28); however, the claim language, as written, does not require that chronological aspect of the sequence. It would have been obvious or inherent to advance the catheter into the left atrium while treating the mitral valve in order to perform the valvuloplasty step. **Bailey** does not explicitly disclose of how the catheter would be positioned in the left atrium. However, **Goar** teaches of a method of accessing the mitral valve through the right and left atrium via a trans-septal puncture (FIG 8). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of **Bailey** with the trans-septal puncture to facilitate the positioning of the catheter in the left atrium.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3773

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Mashack/
Examiner, Art Unit 3773

/Darwin P. Erez/
Primary Examiner, Art Unit 3773